IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of:

Jong Soo Woo et al.

Art Unit: 1612
Examiner: Benjamin Packard
Frederick Krass

Serial No.: 10/597,947

Filed: August 14, 2006

Title: COMPOSITION FOR ORAL ADMINISTRATION OF TAMSULOSIN HYDROCHLORIDE AND CONTROLLED RELEASE GRANULE FORMULATION COMPRISING SAME

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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. SECTION 1.132

I, Jong Soo Woo, being a citizen of the Republic of Korea and presently residing at Daewolmaeul 821-105, #914, Jeongja-dong, Jangan-gu, Suwon-si, Kyungki-do, Republic of Korea, do declare:

That I am one of the co-inventors of the invention disclosed in the above-identified application, and hence am fully familiar with the subject matter therein; and

That I have conducted a series of comparative experiments to demonstrate the remarkable effects of the subject invention, as follows.

Preparation of comparative compositions

Comparative granule formulations 1 to 5 were prepared as follows:

Comparative Example 1: 20 parts by weight of polyvinylacetate based on 1 part by weight of tamsulosin hydrochloride

The procedure of Example 1 of the subject specification was repeated except for using 4 parts by weight of polyvinylacetate, to obtain a sustained release granule of tamsulosin hydrochloride.

Comparative Example 2: 10 parts by weight of polyvinylacetate based on 1 part by weight of tamsulosin hydrochloride

The procedure of Example 1 was repeated except for using 2 parts by weight of polyvinylacetate, to obtain a sustained release granule of tamsulosin hydrochloride.

Comparative Example 3: 1000 parts by weight of polyvinylacetate based on 1 part by weight of tamsulosin hydrochloride

The procedure of Example 1 was repeated except for using 200 parts by weight of polyvinylacetate, to obtain a sustained release granule of tamsulosin hydrochloride.

Comparative Example 4:

The procedure of Example 10 of the subject specification was repeated except for using 133.0 parts by weight of the sustained release granule obtained in Comparative Example 1, to obtain a sustained release coated granule of tamsulosin hydrochloride.

Comparative Example 5:

The procedure of Example 10 was repeated except for using 131.0 parts by weight of the sustained release granule obtained in Comparative Example 2, to obtain a sustained release coated granule of tamsulosin hydrochloride.

Dissolution Test

A dissolution test for tamsulosin hydrochloride was conducted using hard capsules filled with the sustained release granules or coated granules which are obtained in Comparative Examples 1 to 5 above and Examples 1 and 10 of the subject

specification, respectively.

[Testing conditions]

- Apparatus: paddle
- Agitation rate: 100 rpm
- Test solution: pH 6.8(USP), 900ml
- Sampling points: between 5 min and 240 min after the start of the agitation

The samples obtained through the above described procedure were analyzed by repeating the method of Test Example 1 described in the specification. The results are shown in Figs. 2 and 3 below.

Fig 2

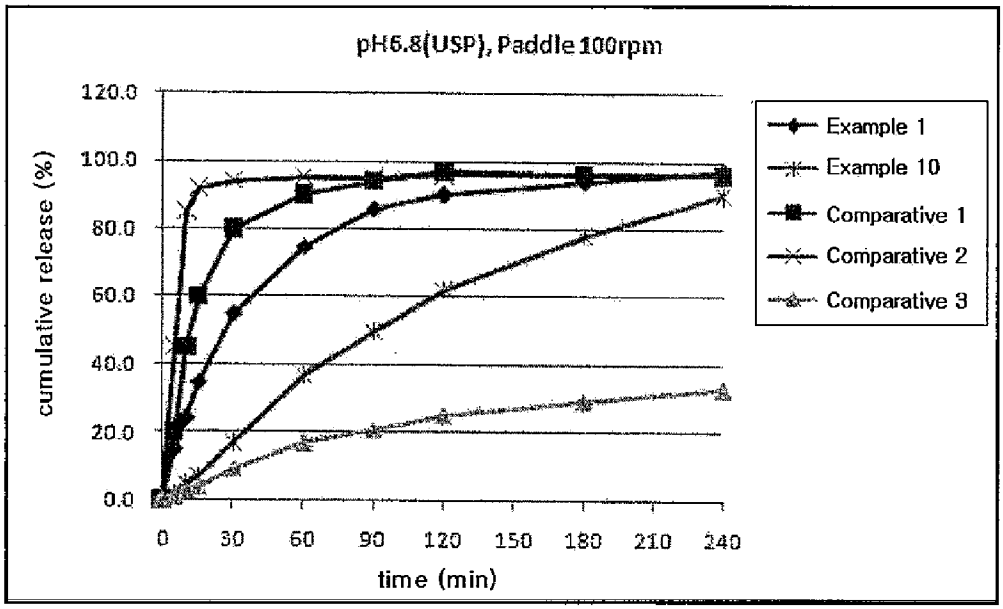
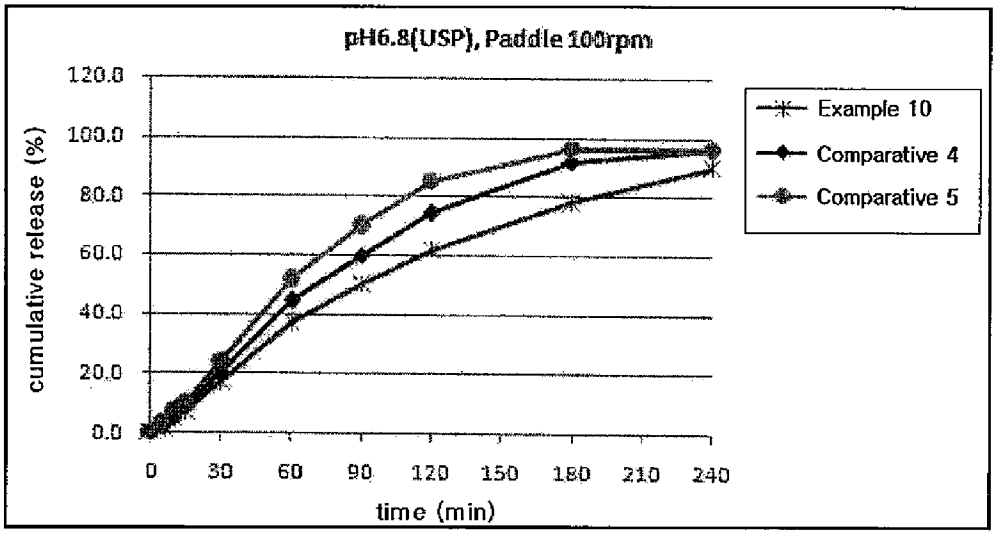


Fig 3



As can be seen from Fig. 2, the formulation of Comparative Example 2 having a weight ratio of 1:10 exhibited an initial burst release of tamsulosin hydrochloride, while the formulation of Comparative Example 1 having a weight ratio of 1:20 exhibited a sustained release characteristic.

Further, in case of Comparative Example 3 having a weight ratio of 1:1000, the release of tamsulosin hydrochloride was too delayed, thereby showing insufficient pharmacological effect.

Further, as shown Fig. 3, the formulation of Comparative Example 5 exhibited a sustained release, since it was obtained by way of coating the formulation of Comparative Example 2 with an additional polyvinylacetate, thereby having a weight ratio of about 1:24.5.

The undersigned declarant further declares that all statement made therein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Dated: September 15, 2010

By: J. S. Woo

Jong Soo Woo